

Notice of Allowability

Application No.

10/809,845

Applicant(s)

SANGITA ET AL.

Examiner

Art Unit

Susannah Chung

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/15/07.
2. ☒ The allowed claim(s) is/are 1-8, 12 and 16-55.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application..

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Claims 1-8, 12, and 16-55 are pending in the instant application. Claims 9-11 and 13-15 are canceled.

Response

Applicant's remarks and amendment to the claims filed on 02/15/2007 are acknowledged.

Restriction

Claims 1-3, 5, 38-40, and 42-47 were examined in the previous office action. In view of the amendment of the claims, claims 4, 6-8, 12, 16-37, 41, and 48-55 have been rejoined. All claims have been examined.

Claims 1-5, 38-40, 41-50, and 53-55 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 7, 8, 12, 16-37, and 51-52 directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 28 January 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

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See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

103 Rejection

Claims 1-3, 5, 38-40, and 42-47 were rejected under 35 USC 103(a) as being obvious over Rotstein et al., US Pat. No. 5,962,531. This rejection is withdrawn in view of the amendment to the claims and response.

112, 2nd Rejection

Claim 1 was rejected under 35 USC 112, 2nd paragraph as being indefinite because of two definitions of R. This rejection is withdrawn in view of the amendment to the claims and response.

112, 1st Rejection

Claims 38-40 and 42-47 have been rejected under 35 USC 112, 1st paragraph because the specification lacked enablement in the treatment of certain disorders. This rejection is withdrawn in view of the amendment to the claims and response.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Mary Katherine Baumeister on 19 March 2007.

The application has been amended as follows:

In claim 38, page 13, line 1, **delete** “for treatment estrogen deficiency, osteoporosis, bone loss, bone formation, hyperlipidaemia or breast cancer” after the word composition.

In claim 38, page 14, line 1, **delete** “thus effective amount of a” after the word a.

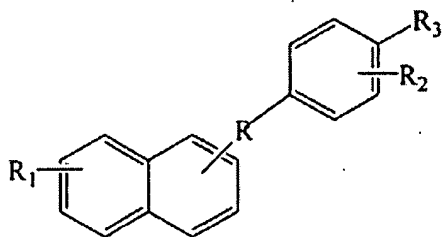
In claim 38, page 15, line 1, **delete** “formulated together with” and **insert** ---and--- before the word a.

In claim 53, pages 19-20, starting line 1, **delete** “for treatment estrogen deficiency, osteoporosis, bone loss, bone formation, hyperlipidaemia or breast cancer, comprising a thus effective amount of” and **insert** ---comprising--- after the word composition.

In claim 53, page 20, line 4, **insert** ---and a pharmaceutically acceptable carrier, inorganic salt, diluent, glidant, lubricant, excipient, sweetening agent, wetting agent, absorbent and/or retardant therefor--- after the word alkyl.

Reasons for Allowance

The present invention is directed to mercaptophenyl naphthyl methane compounds of



formula (I),
depicted in claim 1. The closest prior art of record is U.S. Pat. No. 5,962,531 (Rotstein et al.), which does not teach or provide the requisite motivation to make the instantly claimed compounds, wherein R₃ is attached to the naphthyl ring system, while in the prior art it is attached to the phenyl ring system and R is always CHOH.

The method of treatment claims directed to estrogen deficiency, osteoporosis, bone loss, bone formation, hyperlipidaemia, or breast cancer are supported in the specification on pages 32-

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42, [0110-0143], Biological Evaluation. In particular, the specification on pages 39-42, [0132-0142], provides estrogen agonistic activity and the relative binding affinity data of the compounds for the estrogen receptor is high. On pages 33-35, [0112-0118], of the specification antiosteoporosis (antireoptive) activity in vitro is shown to support the treatment of osteoporosis, bone loss and bone formation. On pages 36-38, [0123-0138], test procedure and data is provided for the evaluation of antiproliferative/cytotoxic activity in vivo. The compounds of the instant application were tested in vivo for anticancer breast activity using the rodent model of hormone responsive breast cancer, namely 7,12-dimethylbenz(a)anthracene (DMBA) induced rat mammary tumor model. The compound is active against mammary tumor as demonstrated by a decrease of the tumor volume.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Chung
Patent Examiner, AU 1626



Joseph K. McKane
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Date: 22 March 2007